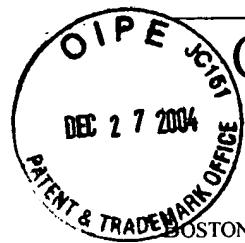


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LAHIVE
 &
COCKFIELD
 L L P



COUNSELLORS AT LAW
 28 STATE STREET
 BOSTON, MASSACHUSETTS 02109-1784
 TELEPHONE (617) 227-7400
 FAX (617) 742-4214
 lc@lahive.com

JOHN A. LAHIVE, JR. (1926-1997)
 THOMAS V. SMURZYNSKI
 GIULIO A. DeCONTI, JR.
 ELIZABETH A. HANLEY
 AMY BAKER MANDRAGOURAS
 ANTHONY A. LAURENTANO
 KEVIN J. CANNING
 JANE E. REMILLARD
 DeANN F. SMITH
 DEBRA J. MILASINCIC, Ph.D.
 WILLIAM A. SCOFIELD, Jr.
 SIBLEY P. REPPERT
 DAVID R. BURNS
 JOHN S. CURRAN
 SEAN D. DETWEILER
 MEGAN E. WILLIAMS, Ph.D.
 HATHAWAY P. RUSSELL
 MARIA LACCO TRIPE ZACHARAKIS, Ph.D.

DANIELLE L. HERRITT
 EUIHOON LEE **
 MANEESH GULATI
 CYNTHIA M. SOROS
 PETER W. DINI, Ph.D.
 MICHAEL J. BASTIAN, Ph.D.
 CHRISTOPHER J. MCKENNA
 VINCENT P. LOCCISANO
 JAMES M. MCKENZIE

SENIOR COUNSEL
 JAMES E. COCKFIELD

OF COUNSEL
 JEREMIAH LYNCH
 JEANNE M. DIGIORGIO
 CYNTHIA L. KANIK, Ph.D.
 JOHN D. LANZA

PATENT AGENTS
 JONATHAN M. SPARKS, Ph.D.
 ANDRINA WILLIAMS ZINK
 CRISTIN E. HOWLEY, Ph.D.
 JILL A. MELLO, Ph.D.
 CHRISTOPHER E. DRABIK
 JAMES H. VELEMA

TECHNICAL SPECIALISTS
 CATHERINE M. BISHOP
 JACOB G. WEINTRAUB
 DEBORAH L. NAGLE, Ph.D.
 A. JACQUELINE WIZEMAN, Ph.D.
 BRIAN C. TRINQUE, Ph.D.
 CHRISTOPHER R. COWLES, Ph.D.
 W. ELANA WANG
 CYNTHIA M. GILBERT
 MEAGHAN L. RICHMOND, Ph.D.

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December 23, 2004

MS Amendment
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, Virginia 22313-1450

Re: U.S. Patent Application No.: 10/722,689
 For: *MODULATION OF HIV REPLICATION BY RNA INTERFERENCE*
 Inventors: Stevenson, Mario, *et al.*
 Filed: November 24, 2003
 Our Ref. No.: UMY-034

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

1. Information Disclosure Statement;
2. PTO Form SB/08;
3. Copies of select publications cited in PTO Form SB/08 (71); and
4. A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

I hereby certify that this correspondence is deposited with the United States Postal Service as first class mail in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on:

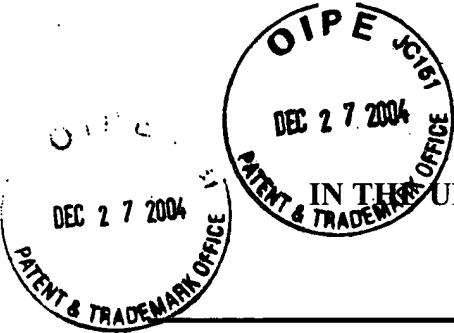
December 23, 2004

Date

Debra J. Milasincic, Esq. Registration No. 46,931

Respectfully submitted,
LAHIVE & COCKFIELD, LLP

Debra J. Milasincic, Esq.
 Registration No. 46,931
 Attorney for Applicants



UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Stevenson, Mario, *et al.*

Serial No.: 10/722,689

Filed: November 24, 2003

For: *MODULATION OF HIV REPLICATION BY RNA INTERFERENCE*

Attorney Docket No.: UMY-034

Group Art Unit: 1645

Examiner: Not Yet Assigned

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

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By

Debra J. Milasincic, Esq.
Registration No. 46,931
Attorney for Applicants

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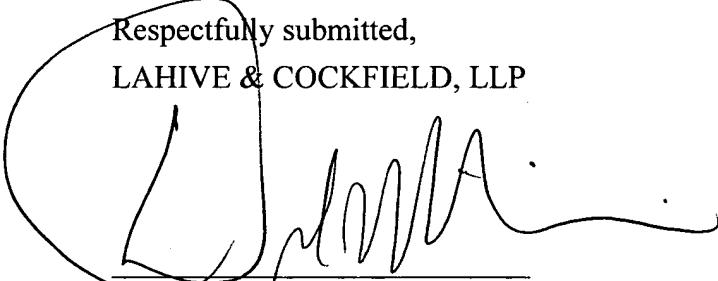
Dear Sir:

Applicants and their Attorney are aware of the following publications and information, listed on the attached PTO Form SB/08, and in accordance with 37 CFR §1.97 hereby submit these publications for the Examiner's consideration. A copy of each cited publication is enclosed. Copies of cited U.S. patents and U.S. publications (Reference ID Nos. A1-A8) are not enclosed with this statement. Copies of foreign patent documents and non-patent literature (Reference ID Nos. A9-E7) are enclosed in accordance with 37 CFR 1.98(a)(2).

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,
LAHIVE & COCKFIELD, LLP



Debra J. Milasincic, Esq.
Registration No. 46,931
Attorney for Applicants

28 State Street
Boston, MA 02109
(617) 227-7400

Date: December 23, 2004

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/722,689
<i>(Use as many sheets as necessary)</i>				Filing Date	November 24, 2003
				First Named Inventor	Stevenson, Mario
				Art Unit	1645
				Examiner Name	Not Yet Assigned
Sheet	1	of	5	Attorney Docket Number	UMY-034

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
A1	5,866,698		02-02-1999	Ecker, et al.	
A2	2003/005944 A1		03-27-2003	Lois-Caballe, et al.	
A3	6,573,099 B2		06-03-2003	Graham	
A4	2003/0124513 A1		07-03-2003	McSwiggen	
A5	2003/0157691 A1		08-21-2003	Qin, et al.	
A6	2003/0175950 A1		09-18-2003	McSwiggen	
A7	2003/0203868 A1		10-30-2003	Bushmann, et al.	
A8	2003/0206887 A1		11-06-2003	Morrissey, et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)			
A9	WO 97/31642		09-04-1997	Akira Kaji	
A10	WO 97/46673		12-11-1997	Novartis	
A11	WO 98/04686		02-05-1998	Day, Robert, et al.	
A12	WO 98/25630		06-18-1998	State University of New York	
A13	WO 99/41355		08-19-1999	State University of New York	
A14	WO 00/31271		06-02-2000	Hismitsu Pharmaceutical Co.	
A15	WO 01/90347		11-29-2001	Syngenix Ltd.	
A16	EP 1 214 945 A2		06-19-2002	RiboPharma AG	
A17	WO 02/068582		09-06-2002	Dongbu Hannong Chemical	
A18	WO 03/033700 A1		04-24-2003	RiboPharma AG	
A19	EP 1 352 960.A1		10-15-2003	Viruvation BV	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
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	A20	Adelman ZN, Sanchez-Vargas I, Travanty EA, Carlson JO, Beaty BJ, Blair CD, Olson KE. RNA silencing of dengue virus type 2 replication in transformed C6/36 mosquito cells transcribing an inverted-repeat RNA derived from the virus genome. J Virol. 2002 Dec;76(24):12925-33.			

Examiner Signature	Date Considered
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	B1	Boden D, Pusch O, Lee F, Tucker L, Shank PR, Ramratnam B. Promoter choice affects the potency of HIV-1 specific RNA interference. Nucleic Acids Res. 2003 Sep 1;31(17):5033-8.			
	B2	Boden D, Pusch O, Lee F, Tucker L, Ramratnam B. Human immunodeficiency virus type 1 escape from RNA interference. J Virol. 2003 Nov;77(21):11531-5.			
	B3	Bradbury, Jane. RNAi is successful as an antiviral in proof of principle experiments. The Lancet. June 29:359:2257.			
	B4	Caplen NJ, Zheng Z, Falgout B, Morgan RA. Inhibition of viral gene expression and replication in mosquito cells by dsRNA-triggered RNA interference. Mol Ther. 2002 Aug;6(2):243-51.			
	B5	Chang J, Taylor JM. Susceptibility of human hepatitis delta virus RNAs to small interfering RNA action. J Virol. 2003 Sep;77(17):9728-31.			
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	B7	Couzin J. RNA interference. Mini RNA molecules shield mouse liver from hepatitis. Science. 2003 Feb 14;299(5609):995.			
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	B10	Garber, Ken. Prescription RNA. Technology Review. December 2002/January 2003. pp. 42-48.			
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	B12	Gitlin L, Karelsky S, Andino R. Short interfering RNA confers intracellular antiviral immunity in human cells. Nature. 2002 Jul 25;418(6896):430-4. Epub 2002 Jun 26.			
	B13	Gitlin L, Andino R. Nucleic acid-based immune system: the antiviral potential of mammalian RNA silencing. J Virol. 2003 Jul;77(13):7159-65.			
	B14	Gummuluru S, Emerman M. Advances in HIV molecular biology. AIDS. 2002;16 Suppl 4:S17-23.			
	B15	Hall AH, Alexander KA. RNA interference of human papillomavirus type 18 E6 and E7 induces senescence in HeLa cells. J Virol. 2003 May;77(10):6066-9.			
	B16	Hu WY, Myers CP, Kilzer JM, Pfaff SL, Bushman FD. Inhibition of retroviral pathogenesis by RNA interference. Curr Biol. 2002 Aug 6;12(15):1301-11.			
	B17	Hutvagner G, McLachlan J, Pasquinelli AE, Balint E, Tuschi T, Zamore PD. A cellular function for the RNA-interference enzyme Dicer in the maturation of the let-7 small temporal RNA. Science. 2001 Aug 3;293(5531):834-8. Epub 2001 Jul 12.			

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				Examiner Name	Not Yet Assigned
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	C1	Hutvagner G, Zamore PD. A microRNA in a multiple-turnover RNAi enzyme complex. <i>Science</i> . 2002 Sep 20;297(5589):2056-60. Epub 2002 Aug 01.				
	C2	J.T. Lab tool may spawn new antiviral drugs. <i>Science News</i> . 2002 August;162:93-94.				
	C3	Jacque JM, Triques K, Stevenson M. Modulation of HIV-1 replication by RNA interference. <i>Nature</i> . 2002 Jul 25;418(6896):435-7. Epub 2002 Jun 26.				
	C4	Joost Haasnoot PC, Cupac D, Berkhout B. Inhibition of virus replication by RNA interference. <i>J Biomed Sci</i> . 2003;10(6 Pt 1):607-16.				
	C5	Lawrence D. RNAi could hold promise in the treatment of HIV. <i>Lancet</i> . 2002 Jun 8;359(9322):2007.				
	C6	Lee NS, Dohjima T, Bauer G, Li H, Li MJ, Ehsani A, Salvaterra P, Rossi J. Expression of small interfering RNAs targeted against HIV-1 rev transcripts in human cells. <i>Nat Biotechnol</i> . 2002 May;20(5):500-5.				
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	C8	Liang XZ, Lucy AP, Ding SW, Wong SM. The p23 protein of hibiscus chlorotic ringspot virus is indispensable for host-specific replication. <i>J Virol</i> . 2002 Dec;76(23):12312-9.				
	C9	Liang X, Zhou Y, Lian J, Nie Q, Jia Z. Effect of inhibitor RNA on intracellular inhibition of viral gene expression in 5'-noncoding region of hepatitis C virus. <i>Zhonghua Nei Ke Za Zhi</i> . 2002 Oct;41(10):660-2. Chinese.				Abst
	C10	Lin SL, Sukasweang S, Chuong CM, Rasheed S, Ying SY. D-RNAi (messenger RNA-antisense DNA interference) as a novel defense system against cancer and viral infections. <i>Curr Cancer Drug Targets</i> . 2001 Nov;1(3):241-7.				
	C11	Lindenbach BD, Rice CM. RNAi targeting an animal virus: news from the front. <i>Mol Cell</i> . 2002 May;9(5):925-7.				
	C12	Martinez MA, Gutierrez A, Armand-Ugon M, Blanco J, Parera M, Gomez J, Clotet B, Este JA. Suppression of chemokine receptor expression by RNA interference allows for inhibition of HIV-1 replication. <i>AIDS</i> . 2002 Dec 6;16(18):2385-90.				
	C13	Martinez MA, Clotet B, Este JA. RNA interference of HIV replication. <i>Trends Immunol</i> . 2002 Dec;23(12):559-61.				
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	C16	Nykanen A, Haley B, Zamore PD. ATP requirements and small interfering RNA structure in the RNA interference pathway. <i>Cell</i> . 2001 Nov 2;107(3):309-21.				
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	D1	Park WS, Miyano-Kurosaki N, Nakajima E, Takaku H. Specific inhibition of HIV-1 gene expression by double-stranded RNA. Nucleic Acids Res Suppl. 2001;(1):219-20.			Abst
	D2	Park WS, Miyano-Kurosaki N, Hayafune M, Nakajima E, Matsuzaki T, Shimada F, Takaku H. Prevention of HIV-1 infection in human peripheral blood mononuclear cells by specific RNA interference. Nucleic Acids Res. 2002 Nov 15;30(22):4830-5.			
	D3	Pomerantz RJ. RNA interference meets HIV-1: will silence be golden? Nat Med. 2002 Jul;8(7):659-60.			
	D4	Pooggin M, Shivaprasad PV, Veluthambi K, Hohn T. RNAi targeting of DNA virus in plants. Nat Biotechnol. 2003 Feb;21(2):131-2.			
	D5	Pusch O, Boden D, Silbermann R, Lee F, Tucker L, Ramrathnam B. Nucleotide sequence homology requirements of HIV-1-specific short hairpin RNA. Nucleic Acids Res. 2003 Nov 15;31(22):6444-9.			
	D6	Roshal M, Kim B, Zhu Y, Nghiem P, Planelles V. Activation of the ATR-mediated DNA damage response by the HIV-1 viral protein R. J Biol Chem. 2003 Jul 11;278(28):25879-86. Epub 2003 May 08.			
	D7	Seo MY, Abrignani S, Houghton M, Han JH. Small interfering RNA-mediated inhibition of hepatitis C virus replication in the human hepatoma cell line Huh-7. J Virol. 2003 Jan;77(1):810-2.			
	D8	Schwarz DS, Hutvagner G, Haley B, Zamore PD. Evidence that siRNAs function as guides, not primers, in the Drosophila and human RNAi pathways. Mol Cell. 2002 Sep;10(3):537-48.			
	D9	Sharp PA, Zamore PD. Molecular biology. RNA interference. Science. 2000 Mar 31;287(5462):2431-3.			
	D10	Shlomai A, Shaul Y. Inhibition of hepatitis B virus expression and replication by RNA interference. Hepatology. 2003 Apr;37(4):764-70.			
	D11	Silva JM, Hammond SM, Hannon GJ. RNA interference: a promising approach to antiviral therapy? Trends Mol Med. 2002 Nov;8(11):505-8.			
	D12	Skipper, M. Interfering with infection. Nature Reviews. 2002. August: 3572-3.			
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	D14	Surabhi RM, Gaynor RB. RNA interference directed against viral and cellular targets inhibits human immunodeficiency Virus Type 1 replication. J Virol. 2002 Dec;76(24):12963-73.			
	D15	Tang H, Peng T, Wong-Staal F. Novel technologies for studying virus-host interaction and discovering new drug targets for HCV and HIV. Curr Opin Pharmacol. 2002 Oct;2(5):541-7.			
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	D17	Tuschl T. Expanding small RNA interference. Nat Biotechnol. 2002 May;20(5):446-8.			
	D18	Valdes VJ, Sampieri A, Sepulveda J, Vaca L. Using double-stranded RNA to prevent in vitro and in vivo viral infections by recombinant baculovirus. J Biol Chem. 2003 May 23;278(21):19317-24. Epub 2003 Mar 19.			

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	E1	Vanitharani R, Chellappan P, Fauquet CM. Short interfering RNA-mediated interference of gene expression and viral DNA accumulation in cultured plant cells. Proc Natl Acad Sci U S A. 2003 Aug 5;100(16):9632-6. Epub 2003 Jul 28.	
	E2	Wang X, McLachlan J, Zamore PD, Hall TM. Modular recognition of RNA by a human pumilio-homology domain. Cell. 2002 Aug 23;110(4):501-12.	
	E3	Waterhouse PM, Graham MW, Wang MB. Virus resistance and gene silencing in plants can be induced by simultaneous expression of sense and antisense RNA. Proc Natl Acad Sci U S A. 1998 Nov 10;95(23):13959-64.	
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	E5	Winstead, Edward. Silencing Genes in HIV. Geonme News Network. June 21, 2002. pp. 1-5. Retrieved from the internet: www.gnn/tigr.org .	
	E6	Yamamoto T, Omoto S, Mizuguchi M, Mizukami H, Okuyama H, Okada N, Saksena NK, Brisibe EA, Otake K, Fuji YR. Double-stranded nef RNA interferes with human immunodeficiency virus type 1 replication. Microbiol Immunol. 2002;46(11):809-17.	
	E7	Gene therapy can destroy HIV. October 10, 2002. Retrieved from Internet: www.msnbc.com/news/747082.asp?cp1=1 .	

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